Attorney's Docket No.: 07763-042001

Applicant: Gennaro et al. Serial No.: 10/009,384 Filed: August 20, 2002

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## Amendments to the Claims

This listing of claims replaces all prior versions and listings of claims in the application.

## Listing of Claims:

1. (Currently amended) An isolated DNA molecule comprising a DNA sequence encoding a polypeptide with an [[first]] amino acid sequence selected from the group consisting of the amino acid sequences of the polypeptides MTSP1, MTSP2, MTSP3, MTSP4, MTSP5, MTSP6, MTSP7, MTSP8, MTSP9, MTSP10, MTSP11, MTSP12, MTSP13, MTSP14, MTSP15, MTSP16, MTSP17, MTSP18, MTSP19, MTSP20, MTSP21, MTSP22, MTSP23, MTSP24, MTSP25, MTSP26, MTSP27, MTSP28, MTSP29, MTSP30, MTSP31, MTSP32, MTSP33, MTSP34, MTSP35, MTSP36, MTSP37, MTSP38, MTSP39, MTSP40, MTSP41, MTSP42, MTSP43, MTSP44, MTSP45, MTSP46, and MTSP47, as depicted in Fig. 1,

or a second amino acid sequence identical to said first amino acid sequence but with conservative substitutions.

wherein said polypeptide has *Mycobacterium tuberculosis* specific antigenic and immunogenic properties.

- 2. (Original) An isolated portion of the DNA molecule of claim 1, said portion encoding a segment of said polypeptide shorter than the full-length polypeptide, said segment having *Mycobacterium tuberculosis* specific antigenic and immunogenic properties.
  - 3. (Original) A vector comprising:
  - (a) the DNA molecule of claim 1; and

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(b) transcriptional and translational regulatory sequences operationally linked to said DNA sequence, said regulatory sequences allowing for expression of the polypeptide encoded by said DNA sequence in a cell.

- 4. (Original) A vector comprising:
- (a) the DNA molecule of claim 2; and
- (b) transcriptional and translational regulatory sequences operationally linked to said DNA sequence, said regulatory sequences allowing for expression of the polypeptide encoded by said DNA sequence in a cell.
  - 5. (Original) A cell transformed with the vector of claim 3.
  - 6. (Original) A cell transformed with the vector of claim 4.
- 7. (Original) A composition comprising the vector of claim 3 and a pharmaceutically acceptable diluent or filler.
- 8. (Original) A composition comprising the vector of claim 4 and a pharmaceutically acceptable diluent or filler.
  - 9. 10. (Cancelled)
- 11. (Currently amended) An isolated polypeptide with an [[first]] amino acid sequence selected from the group consisting of the sequences of the polypeptides MTSP1, MTSP2, MTSP3, MTSP4, MTSP5, MTSP6, MTSP7, MTSP8, MTSP9, MTSP10, MTSP11, MTSP12, MTSP13, MTSP14, MTSP15, MTSP16, MTSP17, MTSP18, MTSP19, MTSP20, MTSP21, MTSP22, MTSP23, MTSP24, MTSP25, MTSP26, MTSP27, MTSP28, MTSP29, MTSP30, MTSP31, MTSP32, MTSP33, MTSP34, MTSP35, MTSP36, MTSP37, MTSP38, MTSP39, MTSP40, MTSP41, MTSP42, MTSP43, MTSP44, MTSP45, MTSP46, and MTSP47, as depicted in Fig. 1,

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or a second amino acid sequence identical to said first amino acid sequence but with conservative substitutions,

wherein said polypeptide has *Mycobacterium tuberculosis* specific antigenic and immunogenic properties.

- 12. (Original) An isolated segment of the polypeptide of claim 11, said segment being shorter than the full-length polypeptide and having *Mycobacterium tuberculosis* specific antigenic and immunogenic properties.
- 13. (Currently amended) A composition comprising the polypeptide of claim 11, or a functional segment thereof, and a pharmaceutically acceptable diluent or filler.
- 14. (Currently amended) A composition comprising the polypeptide of claim 12, or a functional segment thereof, and a pharmaceutically acceptable diluent or filler.
- 15. (Currently amended) A composition comprising at least two polypeptides of the *Mycobacterium tuberculosis* complex, or functional segments thereof, wherein at least one of said at least two polypeptides is the [[sequence]] polypeptide of claim [[1]] 11.
- 16. (Currently amended) A composition comprising at least two polypeptides of the *Mycobacterium tuberculosis* complex, or functional segments thereof, wherein at least one of said at least [[polypeptides]] segments is the segment of claim [[2]] 12.
  - 17. (Currently amended) A method of diagnosis comprising:
- (a) administration of the composition of claim 13 a polypeptide to a subject suspected of having or being susceptible to *Mycobacterium tuberculosis* infection, the polypeptide being selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (b) detecting an immune response in said subject to said [[composition]] <u>polypeptide</u>, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.

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18. (Currently amended) A method of diagnosis comprising:

(a) administration of the composition of claim 14 a polypeptide segment to a subject suspected of having or being susceptible to *Mycobacterium tuberculosis* infection, the segment being a functional segment of the polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and

- (b) detecting an immune response in said subject to said [[composition]] <u>polypeptide</u> <u>segment</u>, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 19. (Currently amended) A method of diagnosis comprising:
- (a) administration of [[the]] <u>a</u> composition [[of claim 15]] to a subject suspected of having or being susceptible to *Mycobacterium tuberculosis* infection, the composition comprising at least two polypeptides of the *Mycobacterium tuberculosis* complex, or functional segments thereof, wherein at least one of said at least two polypeptides is a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (b) detecting an immune response in said subject to said composition as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 20. (Currently amended) A method of diagnosis comprising:
- (a) administration of [[the]] <u>a</u> composition [[of claim 16]] to a subject suspected of having or being susceptible to *Mycobacterium tuberculosis* infection, the composition comprising at least two polypeptides of the *Mycobacterium tuberculosis* complex, or functional segments thereof, wherein at least one of said at least two segments is a functional segment of a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (b) detecting an immune response in said subject to said composition as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.

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21. (Currently amended) A method of diagnosis comprising:

- (a) providing a population of cells comprising CD4 T lymphocytes from a subject;
- (b) providing a population of cells comprising antigen presenting cells (APC) expressing a major histocompatibility complex (MHC) class II molecule expressed by said subject;
- (c) contacting the CD4 lymphocytes of (a) with the APC of (b) in the presence of [[the]] a polypeptide [[of claim 1]] selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (d) determining the ability of said CD4 lymphocytes to respond to said polypeptide, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 22. (Currently amended) A method of diagnosis comprising:
  - (a) providing a population of cells comprising CD4 T lymphocytes from a subject;
- (b) providing a population of cells comprising antigen presenting cells (APC) expressing at least one major histocompatibility complex (MHC) class II molecule expressed by said subject;
- (c) contacting the CD4 lymphocytes of (a) with the APC of (b) in the presence of [[the]] <u>a</u> functional segment of [[claim 2]] <u>a polypeptide selected from the group consisting of MTSP1, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and</u>
- (d) determining the ability of said CD4 lymphocytes to respond to said [[polypeptide]] segment, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 23. (Currently amended) A method of diagnosis comprising:
  - (a) providing a population of cells comprising CD4 T lymphocytes from a subject;
- (b) providing a population of cells comprising antigen presenting cells (APC) expressing at least one major histocompatibility complex (MHC) class II molecule expressed by said subject;

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(c) contacting the CD4 lymphocytes of (a) with the APC of (b) in the presence of [[the]] a composition [[of claim 15]] comprising at least two polypeptides of the *Mycobacterium* tuberculosis complex, or functional segments thereof, wherein at least one of said at least two polypeptides is a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and

- (d) determining the ability of said CD4 lymphocytes to respond to said <u>at least two</u> polypeptides, <u>or functional segments thereof</u>, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 24. (Currently amended) A method of diagnosis comprising:
  - (a) providing a population of cells comprising CD4 T lymphocytes from a subject;
- (b) providing a population of cells comprising antigen presenting cells (APC) expressing at least one major histocompatibility complex (MHC) class II molecule expressed by said subject;
- (c) contacting the CD4 lymphocytes of (a) with the APC of (b) in the presence of [[the]] a composition [[of claim 16]] comprising at least two polypeptides of the *Mycobacterium* tuberculosis complex, or functional segments thereof, wherein at least one of said at least two segments is a functional segment of a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (d) determining the ability of said CD4 lymphocytes to respond to said <u>at least two</u> polypeptides, <u>or functional segments thereof</u>, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 25. (Currently amended) A method of diagnosis comprising:
- (a) contacting the polypeptide of claim 11 with a bodily fluid of a subject with a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (b) detecting the presence of binding of antibody to said polypeptide, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.

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26. (Currently amended) A method of diagnosis comprising:

(a) contacting the segment of claim 12 with a bodily fluid of a subject with a functional segment of a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and

- (b) detecting the presence of binding of antibody to said [[polypeptide]] <u>segment</u>, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 27. (Currently amended) A method of diagnosis comprising:
- (a) contacting the composition of claim 15 with a bodily fluid of a subject with a composition comprising at least two polypeptides of the *Mycobacterium tuberculosis* complex, or functional segments thereof, wherein at least one of said at least two polypeptides is a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (b) detecting the presence of binding of antibody to said [[composition]] at least two polypeptides, or functional segments thereof, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
  - 28. (Currently amended) A method of diagnosis comprising:
- (a) contacting the composition of claim 16 with a bodily fluid of a subject with a composition comprising at least two polypeptides of the *Mycobacterium tuberculosis* complex, or functional segments thereof, wherein at least one of said at least two segments is a functional segment of a polypeptide selected from the group consisting of MTSP1, MTSP21, MTSP23, MTSP36, and MTSP43, as depicted in Fig. 1; and
- (b) detecting the presence of binding of antibody to said [[composition]] at least two polypeptides, or functional segments thereof, as an indication that said subject has or is susceptible to *Mycobacterium tuberculosis* infection.
- 29. (Withdrawn) A method of vaccination comprising administration of the composition of claim 7 to a subject.

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30. (Withdrawn) A method of vaccination comprising administration of the composition of claim 8 to a subject.

- 31. (Withdrawn) A method of vaccination comprising administration of the composition of claim 9 to a subject.
- 32. (Withdrawn) A method of vaccination comprising administration of the composition of claim 10 to a subject.
- 33. (Withdrawn) A method of vaccination comprising administration of the composition of claim 13 to a subject.
- 34. (Withdrawn) A method of vaccination comprising administration of the composition of claim 14 to a subject.
- 35. (Withdrawn) A method of vaccination comprising administration of the composition of claim 15 to a subject.
- 36. (Withdrawn) A method of vaccination comprising administration of the composition of claim 16 to a subject.